

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ROANOKE DIVISION

PAULINE R. MCFARLANE,

Plaintiff,

v.

Civil Action No.: _____

NEW ENGLAND COMPOUNDING
PHARMACY, INC. D/B/A NEW ENGLAND
COMPOUNDING CENTER

Serve: Gregory Conigliaro, Its Registered Agent
697 Waverly Street
Framingham, MA 01701,

MEDICAL SALES MANAGEMENT, INC.

Serve: Secretary of the Commonwealth of
Virginia, Janet Vestal Kelly
Service of Process Department
P.O. Box 2452
Richmond, VA 23218-2452

and

BARRY J. CADDEN,
Serve at: 13 Manchester Drive
Wrentham, MA 02093

Defendants.

COMPLAINT

Pauline Reynolds McFarlane (Mrs. "McFarlane" or "Plaintiff"), by counsel, states this Complaint against New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), Medical Sales Management, Inc. ("MSM"), and Barry J. Cadden ("Cadden") (hereinafter collectively referred to as the "defendants"):

Preliminary Statement

1. This lawsuit arises from the unnecessary fungal meningitis infection and subsequent

hospitalization of Pauline McFarlane. Mrs. McFarlane's physician, Dr. James Leipzig, M.D., prescribed that she receive an epidural steroid injection and a steroid injection in her left hip. Instead of providing needed pain management, the injection caused Mrs. McFarlane to develop fungal meningitis that has completely changed her life.

Mrs. McFarlane became gravely ill and was hospitalized for a period of nearly three weeks because the steroid shot, manufactured, advertised and distributed by the defendants, was adulterated and contaminated with fungus or mold bearing pathogens that were injected into her central nervous system along with the immune system suppressing steroid. As the fungus grew inside Mrs. McFarlane's spinal fluid, she developed fungal meningitis, severely inflaming the tissues lining her brain and spinal cord. Mrs. McFarlane spent almost three weeks in the hospital battling fungal meningitis. This lawsuit seeks compensation from the defendants for Mrs. McFarlane's unnecessary infection and personal injury.

Parties

2. Mrs. McFarlane lives in Roanoke and is a citizen of the Commonwealth of Virginia.
3. NECC is a Massachusetts corporation that maintains its principal place of operations at 697 Waverly Street, in Framingham, Massachusetts.
4. MSM is a Massachusetts corporation that maintains its principal place of operations at 701 Waverly Street, Framingham, Massachusetts.
5. Cadden, who was at all relevant times the responsible pharmacist for NECC, is a Massachusetts resident.

Jurisdiction and Venue

6. This matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

7. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

8. A substantial part of the events or omissions giving rise to this claim occurred in this judicial district.

9. Venue is proper in this Court pursuant to at least 28 U.S.C. § 1391(b)(2).

Factual Background

The Defendants' Operations

10. NECC is jointly owned by Cadden, his wife, Lisa Cadden and her brother, Gregory Conigliaro.

11. The defendants operated a compounding pharmacy in Framingham, Massachusetts.

12. Compounding pharmacies engage in mixing (or "compounding") drug products for specific patients, pursuant to a valid prescription.

13. Because they typically compound drug products in forms that are not commercially available, compounding pharmacies are not regulated by the FDA.

14. Rather, compounding pharmacies are generally regulated under state law applicable to pharmacies and pharmacists. Although it operates in Massachusetts, NECC must also comply with Virginia law in order to fill prescriptions in Virginia. It must be licensed and registered with the Virginia Board of Pharmacy.

15. MSM is a separate corporate entity from NECC. Upon information and belief, at all relevant times, MSM served as the marketing arm for New England Compounding, providing marketing and advertising services, promoting the compounding business at medical trade shows nationwide, "cold-calling" potential customers, calling existing customers, and managing NECC's online operations.

16. Cadden is the pharmacist in charge of NECC's operations, and was listed as such in NECC's registration as a nonresident pharmacy in Virginia.

17. As pharmacist in charge, Cadden was at all relevant times personally responsible to ensure that NECC's operations complied with Virginia laws. Va. Code § 54.1-3434.1 (any non-resident pharmacy "*shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter . . .*") (emphasis added).

18. Furthermore, as pharmacist in charge of NECC, Cadden was at all times personally responsible to supervise NECC's operations at its facility in Framingham, Massachusetts. Va. Code § 54.1-3432 ("Every pharmacy shall be under the *personal supervision* of a pharmacist on the premises of the pharmacy.") (emphasis added).

19. The defendants are in the business of compounding and manufacturing medications and drugs, including methylprednisolone acetate. The brand name of this drug, Depo-Medrol, is produced by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. Other FDA-regulated drug manufacturers produce generic versions of this drug.

20. Rather than producing small quantities of this knock-off Depo-Medrol, NECC produced vast batches of this drug, thousands at a time. It then acted as a wholesale distributor.

21. The defendants compounded and manufactured medications, including methylprednisolone acetate, that were contaminated with fungus, mold and other contaminants.

22. Under Virginia Code §54.1-3435.01(A), non-resident pharmacies that engage in wholesale distribution of prescription drugs into the Commonwealth of Virginia must register with the Virginia Board of Pharmacy, in addition to registering as a non-resident pharmacy.

23. NECC is and was registered in the Commonwealth of Virginia as a non-resident pharmacy, but is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).

24. Under Virginia law, the compounding pharmacist must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code § 54.1-3410.2(E).

25. Pharmacists and pharmacies may not engage in “the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products.” Virginia Code § 54.1-3410.2(H)(2).

26. As well as other drugs, the defendants produced methylprednisolone acetate without preservative, which they then sold to clinics, hospitals and other healthcare providers in bulk, packaging the drug in single dosage vials.

27. Such large-scale production of a commercially available drug is illegal under Virginia Code § 54.1-3410.2(H)(2).

28. NECC is not accredited by the Pharmacy Compounding Accreditation Board (“PCAB”) or any other similar organization, such as The Joint Commission, that offers independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

29. The drug at issue was to be used in epidural steroid injections allowing direct contact with the central nervous system. It was produced from non-sterile ingredients which then had to be rendered sterile as a finished product, thus making the methylprednisolone acetate a high-risk compound. It was also produced without preservatives. Thus, although all drugs should be

produced in a highly sterile environment, these drugs in particular must be. Additionally, sterilization techniques and sterility testing are crucial to properly producing such drugs.

30. However, the defendants purposefully maintained the supposedly sterile NECC pharmacy in an aged building that is surrounded by a waste recycling center owned by one of the co-owners of NECC, Gregory Conigliaro. This facility, called Conigliaro Enterprises, receives many varieties of garbage and waste which are sorted, stored, and manipulated just outside the back door of the NECC facility. A photograph showing the rear wall and backyard of the "pharmacy" is attached as **Exhibit A**.

31. It is difficult to distinguish where NECC ends and the waste recycling center begins, if there is such a distinction in fact; but, the waste facility lists its address as 701 Waverly Street, Framingham, Massachusetts, and operates under the name "Conigliaro Industries." NECC lists its address as 697 Waverly Street. MSM lists its address as 701 Waverly Street, the same as Conigliaro Industries.

32. The conditions in which the defendants produced their products were unsanitary and unsterile. NECC failed to meet basic quality and sterility standards; and it failed to properly test the drugs at issue for sterility prior to releasing them. As a result, thousands of adulterated products manufactured by NECC were then released into the stream of commerce throughout the United States of America, including at least two clinics in the Commonwealth of Virginia.

33. The drug at issue in this case is a steroid which the defendants knew would be injected into patients so as to enter or potentially enter the central nervous system. The defendants also knew that such steroids act as immune-suppressing agents, thus weakening the patient's natural ability fight off pathogens that could possibly be included in the injection. The defendants also knew that the central nervous system is a relatively closed system, making treatment options more

difficult in the event of an adulterated invasion. Notwithstanding this knowledge, the defendants chose to operate NECC's facility in the same complex as the waste facility, chose to produce such drugs in bulk batches (making mistakes more likely), chose not to properly sterilize the drugs, and chose not to have the drugs sufficiently tested by an FDA-approved testing facility before release for sale.

Mrs. McFarlane's Medical Timeline

34. In 2012, Mrs. McFarlane was experiencing significant back pain. After visiting her family practice physician, Dr. Don Brady, she was diagnosed with spinal stenosis, or narrowing of the spine.

35. Mrs. McFarlane was referred to a spinal surgeon in Salem, Virginia named Dr. James Leipzig.

36. After examining her, Dr. Leipzig recommended an epidural steroid injection as a measure to reduce both her pain and the inflammation associated with stenosis. He also recommended a steroid injection in Mrs. McFarlane's left hip.

37. Dr. Leipzig referred Mrs. McFarlane to Insight Imaging – Roanoke, an image-guided pain management practice, for the injections. The typical method for receiving an epidural steroid injection requires radiological facilities that allow the proper placement of the shot in exactly the right place with the assistance of equipment such as a fluoroscope. An anesthesiologist or an interventional radiologist usually performs such a procedure.

38. Mrs. McFarlane received the first epidural steroid injection at the clinic on or about September 13, 2012. She received a steroid injection in her left hip on September 20, 2012.

39. Over the ensuing few weeks Mrs. McFarlane's symptoms seemed to improve, but she began suffering more and more pain as of early October.

40. On or about October 6, NECC issued a recall of its products, including the type of medication that was injected into Mrs. McFarlane.

41. By October 11, 2012, her lower back pain had returned with such intensity that Mrs. McFarlane was admitted to the Emergency Room at Roanoke Memorial Hospital.

42. Because of her medical history, the medical staff performed a lumbar puncture and confirmed that she suffered from fungal meningitis.

43. Mrs. McFarlane was immediately placed on antifungal medication, and was hospitalized from October 11 to October 29, 2012, a period of almost three weeks.

44. Mrs. McFarlane continues to suffer the after-effects of her battle with fungal meningitis.

45. Mrs. McFarlane's fungal meningitis was a direct and proximate result of having methylprednisolone acetate made by the defendants and contaminated with fungus, mold and other contaminants injected into her spinal cavity.

46. As a proximate result of the defendants' actions, Mrs. McFarlane has suffered and continues to suffer serious bodily harm, mental anguish, economic loss (including but not limited to medical expenses) and other damages.

COUNT I: NEGLIGENCE PER SE

47. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

48. Virginia Code Section 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.

49. Virginia law also establishes that:

... the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care

prescribed by a legislative body. A party relying on negligence *per se* does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Halterman v. Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982)

Schlimmer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

50. Virginia Code Sections 54.1-3400 *et seq.* (collectively known as “The Drug Control Act”) are statutes enacted for public safety, in that they protect the public from the release of substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of Virginia commerce.

51. As a Virginia resident and consumer of a drug regulated by the Virginia Drug Control Act, McFarlane belongs to the class of persons for whose benefit those statutes were enacted.

52. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code §54.1-3461(A)(2).

53. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code §54.1-3461(B).

54. By manufacturing and selling an adulterated drug into the stream of Virginia commerce, the defendants violated Virginia Code §§ 54.1-3457(1), which is part of the Virginia Drug Control Act.

55. By negligently adulterating a drug, the defendants violated Virginia Code §§ 54.1-3457(2), which is part of the Virginia Drug Control Act.

56. By failing to adhere to proper quality control standards in producing the drug given to Mrs. McFarlane, the defendants failed to comply with USP-NF standards in violation of Virginia Code § 54.1-3410.2(E).

57. By engaging in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license to do so issued by the Virginia Board of Pharmacy, the defendants violated Virginia Code § 54.1-3435, which is part of the Virginia Drug Control Act.

58. As pharmacist in charge, defendant Cadden was personally responsible for ensuring that NECC did not violate the provisions of the Virginia Drug Control Act. (Va. Code § 54.1-3432).

59. The defendants' actions violating Va. Code §§ 54.1-3457(1) and (2), 54.1-3410.2(E), and 54.1-3435 proximately caused Mrs. McFarlane's fungal meningitis. Her illness occurred as a direct and proximate result of having the defendants' adulterated drug containing a fungal pathogen injected directly into her central nervous system.

60. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.

61. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in this Commonwealth without registration belongs to the category of harms against which Virginia Drug Control Act was designed to protect

62. United States Code §§ 21 U.S.C. 301 *et seq.* (collectively known as “The Federal Food, Drug and Cosmetic Act” or “FDCA”) are statutes enacted for public safety, in that they protect the public from the release of adulterated, substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of U.S. Commerce.

63. Therefore, because the defendants’ actions violating each of the above statutes (Virginia Code § 54.1-3457(1), Virginia Code § 54.1-3457(2) and Virginia Code § 54.1-3435)) caused her fungal meningitis and constitute negligence *per se*, Mrs. McFarlane is entitled to recovery of damages for the serious bodily harm, mental anguish and economic loss (including but not limited to medical and other expenses) and other damages she suffered as a result of those actions.

COUNT II: NEGLIGENT MANUFACTURE

64. Plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

65. The defendants owed a duty to Mrs. McFarlane, all other foreseeable users of their products, and the public in general to timely and properly:

- a. operate in a clean and sterile environment with properly functioning equipment;
- b. establish quality control measures;
- c. implement quality control measures;
- d. manufacture uncontaminated products;
- e. obtain representative sterility testing for their products for contamination prior to releasing the products into the stream of commerce;
- f. refrain from releasing contaminated products into the stream of commerce;
- g. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC’s co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by

contact with spores or other contaminants contained in the waste recycling center;

- h. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
- i. refrain from engaging in any other act or omission determined during the course of discovery.

66. The defendants breached the above duties and acted negligently, in at least the following ways, by failing to timely and properly:

- j. operate in a clean and sterile environment with properly functioning equipment;
- k. establish quality control measures;
- l. implement quality control measures;
- m. manufacture uncontaminated products;
- n. quality test their products for contamination prior to releasing the products into the stream of commerce;
- o. refrain from releasing contaminated products into the stream of commerce;
- p. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC's co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by contact with spores or other contaminants contained in the waste recycling center;
- q. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
- r. refrain from engaging in any other act or omission determined during the course of discovery.

67. The product methylprednisolone acetate administered to Mrs. McFarlane was not reasonably safe at the time it left the defendants' control.

68. At the time the product left the control of the defendants, a feasible and reasonably implementable alternative production practice was available that would have prevented the harm

caused to Mrs. McFarlane without significantly impairing the usefulness or desirability of the product and without creating equal or greater risk of harm to others.

69. Mrs. McFarlane's infection and hospitalization occurred as a direct and proximate result of the defendants' breaches of their duties to her listed above.

COUNT III: STRICT LIABILITY

70. The plaintiff hereby incorporates each of the preceding paragraphs as if set out fully herein.

71. The defendants manufactured and sold a product that was inherently dangerous for any human use, particularly those involving introduction of the tainted drug into the central nervous system.

72. The inherently dangerous nature of the product was present at the time the product left the defendants' control.

73. Mrs. McFarlane's infection and hospitalization were directly and proximately caused by the introduction of the defendants' inherently dangerous product into her body.

COUNT IV: NEGLIGENT FAILURE TO WARN

74. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

75. The defendants were aware that NECC's production quantities exceeded amounts in which they could properly implement necessary quality controls.

76. The defendants knew or had reason to know that the drug given to Mrs. McFarlane was not produced under conditions that could reasonably ensure quality and sterility.

77. On information and belief, the defendants chose not to obtain independent sterility test results from a representative sampling of the applicable batch of this drug from a third party

sterility testing facility as other compounding pharmacies do before releasing such drugs. The size of the batches at issue made any such sampling (if done) representative of the thousands of dosages created.

78. The defendants knew or had reason to know that compounding medications surrounded by the owner's garbage recycling center would result in increased chances of contaminating such drugs before and during the manufacturing process. These circumstances, while unreasonable and unbelievable under any scenario, further heightened the need to adhere to strict safety, quality, sterility and testing protocols. But, none of this was done. As a result, it was not a matter of "if" adulterated drugs would be produced and sold by NECC, but instead, a matter of when such would occur or when it would occur to such an extent that illness or death resulted. NECC was engaged in what amounted to "Russian-Roulette" with its practices.

79. Because of their knowledge of those issues, as well as other things, the defendants knew or had reason to know that their product, the methylprednisolone acetate, was dangerous for its intended uses.

80. The defendants had no reason to believe that Mrs. McFarlane would realize the dangerous condition of the methylprednisolone acetate.

81. Mrs. McFarlane could not possibly have contemplated or anticipated the dangerousness of the defendants' product, as it was contained in a single, unremarkable dosage vial.

82. By engaging in the acts and omissions described above, and by failing to inform the buyers and foreseeable users of the contamination of the methylprednisolone acetate, the defendants failed to exercise reasonable care to inform users of the dangers associated with the product's use.

83. Mrs. McFarlane's infection and hospitalization occurred as a direct and proximate result of the defendants' failure to warn.

COUNT V: GROSS NEGLIGENCE

84. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

85. Each of the foregoing acts and omissions by the defendants went beyond mere thoughtlessness, inadvertence or error of judgment.

86. Such acts and omissions constituted such an utter disregard for the rights of others, and such an utter disregard for prudence, that they amount to complete neglect of the safety of others, including Mrs. McFarlane. The defendants' acts and omissions were a heedless and palpable violation of their legal duties respecting Mrs. McFarlane's rights. Frazier v. City of Norfolk, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).

87. Mrs. McFarlane's infection and hospitalization occurred as a direct and proximate result of the defendants' grossly negligent acts and omissions.

COUNT VI: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

88. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

89. The defendants had a duty to buyers and foreseeable users such as Mrs. McFarlane to provide a product that was not unreasonably dangerous for the use for which it was intended, and was not unreasonably dangerous for other foreseeable uses.

90. Despite that duty, the methylprednisolone acetate was unreasonably dangerous for the use for which it was intended—epidural injection into the bodies of patients, including Mrs. McFarlane—as well as other reasonably foreseeable uses.

91. The methylprednisolone acetate was unreasonably dangerous for the above-stated uses at the time the product left the defendants' hands.

92. The unreasonably dangerous condition of the methylprednisolone acetate directly and proximately caused Mrs. McFarlane's fungal meningitis.

**COUNT VII: BREACH OF IMPLIED
WARRANTY OF USE FOR A PARTICULAR PURPOSE**

93. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

94. The defendants have heavily marketed both NECC itself and the product methylprednisolone acetate at medical trade shows and the like for use in the pain management setting, including but not limited to inclusion in epidural injections for back pain relief.

95. The defendants knew or had reason to know that the intermediate buyer, Insight Imaging, planned to use the methylprednisolone acetate in administering epidural injections to patients.

96. As such, the defendants knew or had reason to know the particular purpose for which the methylprednisolone acetate was purchased.

97. The defendants had reason to know that their skill or judgment was being relied upon to provide appropriate and reasonably safe goods.

98. At the time of the sale, the methylprednisolone acetate failed to satisfy the purpose contemplated at the time of sale—to be injected into the central nervous systems of patients such as Mrs. McFarlane without causing those patients to suffer unanticipated and unreasonably unsafe side-effects, e.g., fungal meningitis.

99. The failure of the product to satisfy the purpose contemplated at the time of sale proximately caused Mrs. McFarlane's fungal meningitis.

COUNT VIII: MEDICAL NEGLIGENCE
(defendant Cadden)

100. Plaintiff repeats and re-alleges all allegations contained in the preceding paragraphs as if they were fully set forth herein.

101. As director of pharmacy and licensed pharmacist in charge of NECC's operations, Cadden was at all relevant times acting as NECC's agent and / or principal.

102. Cadden had a duty to Mrs. McFarlane and other patients receiving these injections to utilize basic safety and cleanliness standards in the drug manufacturing processes.

103. Cadden had a duty to Mrs. McFarlane and other patients receiving these injections to exercise reasonable care to ensure that the drugs NECC manufactured were sterile and were not adulterated.

104. Cadden breached his duties to Mrs. McFarlane. He failed to utilize basic safety and cleanliness standards in the drug manufacturing processes, and he failed to exercise reasonable care to ensure that the drugs he and NECC manufactured were sterile and not adulterated.

105. Cadden's breaches of duty to Mrs. McFarlane proximately caused her fungal meningitis.

106. The plaintiff has suffered extreme mental anguish, serious bodily harm, and has incurred and will continue to incur significant expenses, including but not limited to medical expenses.

WHEREFORE, Pauline R. McFarlane, by counsel, moves this Court for judgment against the defendants, jointly and severally, in the amount of \$5,000,000 plus taxable costs with pre- and post-verdict interest on all of these amounts, as well as \$350,000 in punitive damages.

PLAINTIFF REQUESTS A TRIAL BY JURY ON ALL ISSUES.

PAULINE REYNOLDS MCFARLANE,

/s/ J. Scott Sexton

By Counsel

J. Scott Sexton, Esq. (VSB No. 29284)
Anthony M. Russell (VSB No. 44505)
Charles H. Smith, III (VSB No. 32891)
Benjamin D. Byrd (VSB No. 76560)
Daniel R. Sullivan, Esq. (VSB No. 81550)
GENTRY LOCKE RAKES & MOORE, LLP
10 Franklin Road, S.E., Suite 800
P. O. Box 40013
Roanoke, Virginia 24022-0013
(540) 983-9300
FAX (540) 983-9400
sexton@gentrylocke.com
russell@gentrylocke.com
smith@gentrylocke.com
byrd@gentrylocke.com
sullivan@gentrylocke.com

Counsel for Pauline Reynolds McFarlane



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JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Pauline R. McFarlane

(b) County of Residence of First Listed Plaintiff Roanoke
(EXCEPT IN U.S. PLAINTIFF CASES)(c) Attorney's (Firm Name, Address, and Telephone Number) 540-983-9300
J. Scott Sexton, Esq. / Gentry Locke Rakes & Moore, LLP
10 Franklin Road SE, Suite 800, Roanoke, VA 24011DEFENDANTS New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, Medical Sales Management, Inc. and Barry J. CaddenCounty of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- (For Diversity Cases Only)
- | | | | | | |
|---|---|---------------------------------------|---|--------------------------------|---------------------------------------|
| Citizen of This State | PTF <input checked="" type="checkbox"/> 1 | DEF <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State | PTF <input type="checkbox"/> 4 | DEF <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	FOREIGN TORTS <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	PROPERTY RIGHTS <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	OTHER TORTS <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
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V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

29 U.S.C. 1332(a) - Diversity

Brief description of cause:

Injuries caused by tainted steroid

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND \$5,000,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

11676473

AMOUNT

350.00

APPLYING IFP

JUDGE

TURK

MAG. JUDGE

7:12-CV-00605